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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,116	09/10/2003	Daniel M. Lafontaine	10527-429004	3548
26191	7590	01/18/2005	EXAMINER	
FISH & RICHARDSON P.C. 3300 DAIN RAUSCHER PLAZA 60 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402			GIBSON, ROY DEAN	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/659,116	LAFONTAINE, DANIEL M.	
	Examiner Roy D. Gibson	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 28,30-32 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 28,30-32 and 36-41 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 6,648,878. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely broader.

Claims 38 and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13 and 15 of U.S. Patent No. 6,290,696. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely broader.

***Claim Rejections - 35 USC § 112***

Claims 30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 recites the limitation "balloon" in line 2. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests this claim should depend from claim 29 to correct this. Claim 32 recites the limitation "cooling member" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in–
  - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
  - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 28 and 38-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Saab (5,624,392).

As to claim 28, Saab discloses a heat transfer catheter for heating or cooling comprising:

a shaft (catheter tube # 12); a cooling chamber (Figure 3, region # 70 and inner member or inside wall of # 72); a coolant intake tube (formed by the inner wall of inner sleeve # 14) disposed within the shaft; and exhaust tube (formed by the outer wall of inner sleeve # 14 and having a distal opening in fluid communication with the inner member of the cooling chamber (col. 4, line 64-col. 5, line 5, col. 8, line 2-45 and col. 11, line 13-col. 12, line 29).

As to claims 38-39, Saab discloses a method of causing cold-induced necrosis, comprising the steps essentially as claimed where reference to a tumor could inherently also be a lesion (col. 11, lines 13-34); wherein it would be inherent in the method to drain the coolant from the cooling chamber through the exhaust tube.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Rubinsky et al. (5,334,181). Saab fails to disclose a shaft that is at least in part surrounded by an insulating sheath which in part defines a vacuum lumen. However, Rubinsky et al. further teach that in the configuration of cryoplasty catheters an insulating or vacuum lumen (col. 7, lines 56-62) over part of the shaft permits the cooling to be confined to the targeted tissue at the distal end of the catheter. Therefore,

at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Saab, as taught by Rubinsky et al. to provide an insulating sheath that defines a vacuum lumen.

Claim 32 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Varney (5,078,713). Saab does not disclose a temperature sensor (thermal-resistive sensor) disposed proximate the cooling chamber. However, Varney teaches a temperature sensor (26) can be readily attached to a device such as described by Saab to sense temperature (col. 3, lines 32-36). Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art of medical catheters to modify the Saab device by providing the temperature sensor proximate the cooling chamber.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saab and Varney as applied to claim 32 above, and further in view of Rubinsky et al. who teaches the advantages of a vacuum lumen as detailed above in the rejection of claim 31.

Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab. Saab discloses the device can be for cooling or heating of remote locations within the human body by delivering a coolant through the coolant intake tube to the cooling chamber by using various gases or liquids such as Freon, etc. (col. 9, line 66-col. 10,

line 10) depending upon the procedure and to include freezing the target tissue. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to provide the device with the appropriate fluid to cool the lesion to the range of about -40° C to about 20° C as required including freezing the target tissue.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Roy D. Gibson  
Primary Examiner  
Art Unit 3739

January 14, 2005